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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)	
	10/598,229	EISELE, FLORIAN	
Office Action Summary	Examiner	Art Unit	
	RONALD J. HUPCZEY, JR.	3739	
The MAILING DATE of this communication Period for Reply	appears on the cover sheet with t	he correspondence address	
A SHORTENED STATUTORY PERIOD FOR REWHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the material patent term adjustment. See 37 CFR 1.704(b).	E DATE OF THIS COMMUNICAT R 1.136(a). In no event, however, may a reply riod will apply and will expire SIX (6) MONTHS atute, cause the application to become ABAND	TION. be timely filed from the mailing date of this communication. ONED (35 U.S.C. § 133).	
Status			
Responsive to communication(s) filed on 30 This action is FINAL . 2b) ☐ T Since this application is in condition for allow closed in accordance with the practice under	This action is non-final. wance except for formal matters		
Disposition of Claims			
4) ☐ Claim(s) 1-6 and 8-20 is/are pending in the 4a) Of the above claim(s) is/are witho 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-6 and 8-20 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and	drawn from consideration.		
Application Papers			
9) The specification is objected to by the Exam 10) The drawing(s) filed on is/are: a) a Applicant may not request that any objection to to Replacement drawing sheet(s) including the cort 11) The oath or declaration is objected to by the	accepted or b) objected to by the drawing(s) be held in abeyance. rection is required if the drawing(s) is	See 37 CFR 1.85(a). s objected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
12) ☐ Acknowledgment is made of a claim for fore a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents. ☐ Certified copies of the priority documents. ☐ Copies of the certified copies of the papplication from the International Bure * See the attached detailed Office action for a	ents have been received. ents have been received in Appli priority documents have been rec reau (PCT Rule 17.2(a)).	ication No eived in this National Stage	
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Ma	nary (PTO-413) ail Date nal Patent Application	

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DETAILED ACTION

1. Applicant's amendments and remarks, received on April 30th, 2009, have been fully considered by the examiner. Claims 1-6 and 8-20 are currently pending with claims 1-3, 5-6, 8, 10 and 13 amended, claim 7 cancelled and claims 18-20 newly added. Applicant's amendment to claim 13 obviates the previously filed objection to the claim. Additionally, Applicant's amendment to claim 13 and remarks on page 5 of the response obviates the rejections under 35 U.S.C. 112, 1st and 2nd paragraphs. The following is a complete response to the April 30th, 2009 communication.

Claim Rejections - 35 USC § 112

2. Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 18, the limitation therein of "... by one of continuous and stepwise expansion." is unclear and confusing. Specifically, it is unclear is the defined expansion is in reference to the treatment electrodes expansion as similarly defined in claim 1 or with regard to the second treatment electrode, the HF coagulation current is conducted by such expansion. Additionally, if the latter is the case, it is unclear as to how coagulation current stepwise or continuous expansion of the current is achieved. Claims 19 and 20 are rejected due to their dependency on the above rejected claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. Claims 1, 6, 8-13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson et al (US Pat. No. 5,797,903).

Regarding claim 1, Swanson discloses an apparatus (system 10) comprising a first threedimensional treatment electrode (electrode body 20 in conjunction with electrode 30) that can be expanded to various states of expansion during use (various states occurring from expansion from collapsed state to expanded state, see col. 5; 12-18) and is capable to conduct an HF coagulation current into said tissue, the treatment electrode being formed such that by one of continuous and stepwise expansion of said electrode it can be kept in constant electrical contact with the tissue during coagulation (electrode body 20 being expanded continuously from a collapsed to expanded state to maintain contact with tissue, see at least col. 5; 12-18) wherein the treatment electrode comprises one of an elastically stretchable and an unfoldable surface element (electrode body 20 which enlarges/expands as internal pressure builds within) that defines a hydraulically separate interior space (see figure 4, space indicated inside electrode body 20 indicated at 38) to which an internal pressure can be applied to expand said surface element and thereby said treatment electrode.

Regarding claim 6, Swanson discloses the inclusion of a liquid supply (supplied through lumen 34, port 36) through which an electrically conductive liquid (liquid 38 in figure 4) can be delivered to said surface element treatment electrode and a current supply device (radiofrequency generator 40, signal wire 32) capable of delivering said HF coagulation current to said treatment electrode in such a way that said HF treatment current conducted to the liquid that is passing through the treatment electrode (see col. 6; 15-26).

Regarding claim 8, Swanson discloses the surface element to be in the form of a sphere (see figures 2-4).

Regarding claim 9, Swanson discloses the treatment electrode to be constructed in the form of a balloon catheter (see figures 2-4 and col. 5; 12-18 describing balloon-like expansion of body **20**).

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Regarding claim 10, Swanson discloses for the surface element to be capable of being filled with said electrically conductive liquid (see col. 5; 11-18 and col. 6; 15-48).

Regarding claim 11, Swanson discloses the electrically conductive fluid to be comprised of a viscosity modifying substance (see col. 11; 53-59).

Regarding claim 12, Swanson discloses for the treatment electrode to be made of a thermally stable material in the form of one of a film, a felt and a woven fabric (see col. 7; 66 – col. 8; 34).

Regarding claim 13, Swanson discloses for the interior space to be enclosed by an expandable auxiliary body (sealed bladders 64) that hydraulically separates said surface element from said interior space and for the surface element to be constructed in several layers such that in an inner layer electrically conductive liquid directed towards an outer surface of the element and in an outer layer electrically conductive liquid can be directed perpendicular to the outer surface of the element (inner layer formed by bladders 64, outer layer formed by electrode body 20, see col. 18; 44-57).

Regarding claim 15, Swanson discloses the electrode to be capable being supplied with a cutting current (electrode body 20 in conjunction with electrode 30). The Examiner notes that Applicant has claimed a statement of intended use, i.e. "adapted to be supplied...". Such limitations fail to structurally distinguish the claims from the prior art of record which is capable

of being used as desired. Since the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 16, Swanson discloses the thermally stable material is comprised of tetrafluoroethylene (see col. 7; 66 – col. 8; 5).

4. Claims 1, 6 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Koblish et al (US Pat. No. 6,837,885 B2).

Regarding claim 1, Koblish discloses an apparatus comprising a first three-dimensional treatment electrode (inflatable therapeutic element 14 with non-porous region 30, porous region 26 and in relation with electrode 32) that can be expanded to various states of expansion during use (various states occurring from expansion from collapsed state to expanded state) and is capable to conduct an HF coagulation current into said tissue, the treatment electrode being formed such that by one of continuous and stepwise expansion of said electrode it can be kept in constant electrical contact with the tissue during coagulation (inflatable therapeutic element 14 filled with various levels of pressure to maintain tissue contact, see col. 10; 9-30) wherein the treatment electrode comprises one of an elastically stretchable and an unfoldable surface element (inflatable therapeutic element 14 which enlarges/expands as pressure is increased, see col. 10; 9-30) that defines a hydraulically separate interior space (see figure 3, internal space of inflatable therapeutic element 14) to which an internal pressure can be applied to expand said surface element and thereby said treatment electrode.

Regarding claim 6, Koblish discloses the inclusion of a liquid supply (supplied by fluid supply device 72) through which an electrically conductive liquid (liquid 38 in figure 4) can be delivered to said surface element treatment electrode and a current supply device (control

apparatus **41**) capable of delivering said HF coagulation current to said treatment electrode in such a way that said HF treatment current conducted to the liquid that is passing through the treatment electrode (see col. 7; 36- col. 8;8).

Regarding claim 14, Koblish discloses for a suction device to be provided that sucks away liquid (fluid delivery device 72 in conjunction with ventilation lumen 58).

5. Claims 1, 5 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Stern et al (US Pat. No. 7,150,745 B2).

Regarding claim 1, Stern discloses an apparatus comprising a first three-dimensional treatment electrode (see figures 2-4, electrode array 30/112 on electrode support 24/110 on inflatable balloon 28/116) that can be expanded to various states of expansion during use (see col. 13; 6-10) and is capable to conduct an HF coagulation current into said tissue (see col. 10; 4-12 and col. 13; 40-43), the treatment electrode being formed such that by one of continuous and stepwise expansion of said electrode it can be kept in constant electrical contact with the tissue during coagulation (see col. 13; 47-56) wherein the treatment electrode comprises one of an elastically stretchable and an unfoldable surface element (see col. 13; 47-56, electrode array 30/112 on electrode support 24/110 on inflatable balloon 28/116) that defines a hydraulically separate interior space (see figure 4) to which an internal pressure can be applied to expand said surface element and thereby said treatment electrode (see col. 13; 32-59).

Regarding claim 5, Stern disclose for measurement device to detect the state of expansion of the electrode (see col. 12; 4-12).

Regarding claim 15, Stern discloses the apparatus capable of being supplied with a cutting current (see col. 10; 4-12 and col. 13; 40-43).

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Phan et al (US Pat. Pub. 2003/0130572 A1).

Regarding claim 1, Phan discloses an apparatus comprising a first three-dimensional treatment electrode (see figures 4-5, porous electrode 64) that can be expanded to various states of expansion during use (during inflation from a collapsed state to an expanded state) and is capable to conduct an HF coagulation current into said tissue (RF energy, see paragraph [0070]), the treatment electrode being formed such that by one of continuous and stepwise expansion of said electrode it can be kept in constant electrical contact with the tissue during coagulation (see paragraphs [0059]-[0060], continuous expansion to an expanded state) wherein the treatment electrode comprises one of an elastically stretchable and an unfoldable surface element (see paragraphs [0069] and [0075]) that defines a hydraulically separate interior space (internal portion of electrode 64) to which an internal pressure can be applied to expand said surface element and thereby said treatment electrode (see paragraph [0069]).

Claim Rejections - 35 USC § 103

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US Pat. No. 5,707,903).

Regarding claim 17, Swanson fails to specifically recite the limitation of a partition layer placed in between the inner layer and outer layer. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the three-dimensional body of a plurality of layers with each layer suited, as evidenced by Swanson (see col. 8; 50-63), to provide for a desired level1 of liquid perfusion and to create a structure which is capable of withstanding a desired amount of internal inflation pressure while not ripping or tearing.

8. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koblish et al (US Pat. No. 6,837,885 B2) as applied to claim 1 above, and further in view of Abele et al (US Pat. No. 5,496,311).

Regarding claim 2, Koblish discloses a control device (control apparatus 41, fluid supply device 72) functioning to monitor and control coagulation current as well as controlling the expansion of the body to maintain an adequate level of contact (see col. 8; 9-30 and col. 9; 52 col. 10; 26). Koblish further discloses the control apparatus to function via measurement of fluid temperatures internal to the body via a thermistor (see col. 8; 9-22). Koblish fails to specifically detail the controlling of the degree of expansion of the body dependent on the coagulation current. Abele discloses a similar expandable system consisting of a three-dimensional body consisting of at least one electrode (see figure 3). Abele further discloses the controlling of the coagulation current by the monitoring of the temperature of the fluid internal the body (see col. 9; 42-53) and various levels of control of the pressure and volume of fluid within the body (see col. 9; 54 - col. 10; 4). Additionally Abele discloses the assessment of contact between the body and a target portion of tissue to be capable of being assessed by the change in power it requires to maintain a given temperature of fluid with a body (see col. 13; 57 - col. 14; 2) and the subsequent control of the system based on the change in power sensed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a control device and fluid control system such as that of Abele in conjunction with the device of Koblish to provide for a device which controls the expansion if the body dependent on the coagulation current. The establishing and maintaining of contact in such RF procedures is well known to prevent the charring of tissue and to effectively convey the energy transmitted to the

conductive fluid into the target tissue. Furthermore, as evidenced by Abele, the maintaining of a desired level of contact can effectuate control over the depth of heating in a target portion of tissue and reduce if not stop the blood flow in the target area thereby reducing the amount of cooling caused by the flow.

Regarding claim 3, Koblish discloses the control device adapted to enable the adjustment of the current density of the coagulation current between the electrode and tissue (see col. 8; 9-30).

Regarding claim 4, Koblish discloses the control device permitting the current density and state of expansion to be adjusted independently (fluid supply device 72 and control apparatus 41) such as the fluid supply device maintaining a constant volume and the control apparatus functioning on power control via sensed values from the thermistor.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US Pat. No. 5,797,903) as applied to claim 1 above, and further in view of Lennox et al (US Pat. No. 5,545,195).

Regarding claim 5, Swanson discloses a liquid-supply device (lumen 34, port 36) through which electrically conductive fluid can be delivered to the treatment electrode but fails to disclose a measurement device to detect the state of expansion of the three-dimensional body. Lennox discloses an analogous device containing a three-dimensional body which can be expanded to a plurality of expanded states containing at least one electrode. Lennox further discloses a measurement device to detect the state of expansion of the three-dimensional body (syringe 224 and its displacement, see col. 4; 2-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide such a fluid supply

and monitoring device as that of Lennox in conjunction with the device of Swanson in order to both provide fluid to the three-dimensional body of Swanson and adequately assess the level of expansion of the three-dimensional body. Additionally, the provision of monitoring the expansion of the three-dimensional body of a device as Swanson and Lennox is well known in the art and such monitoring ensures the three-dimensional body is expanded to a safe level, not exposed to excessive amounts of pressure and does not apply excess pressure to the body lumen or space in which it is inserted.

10. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al (US Pat. No. 7,150,745 B2) as applied to claim 1 above, and further in view of Abele et al (US Pat. No. 5,496,311).

Regarding claim 2, Stern discloses the system of above claim 1 and further discloses the monitoring of the degree of expansion of the treatment electrode. Stern fails to disclose a control device which controls the degree of expansion in relation to the coagulation current. Abele discloses a similar treatment apparatus containing an expandable member (catheter balloon 8) with an associated electrode structure (rf heating contacts 22, 24), a generator for producing and delivering energy to the electrode structure (control module 54, rf power supply 50) and for the generator to be capable of automatically inflating the expansion member inside a body lumen and controlling the pressure inside the expansion member during treatment of the tissue (see col. 7; 51- col. 8;21). Abele further discloses the inclusion of a pump (syringe 2, pressure source 33) for automatically inflating/deflating the expansion member. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the control device of Abele in conjunction with the electrode structure/expandable member of Stern

to provide for a device which delivers energy to a target portion of tissue via a contacting electrode structure and which maintains a safe and effective level of pressure inside the expansion member to effectuate treatment to the target portion of tissue. The control of the inflation/pressure is important in maintaining sufficient electrical contact between the electrode structure and the target tissue resulting in a more even distribution of electrosurgical energy to the tissue Additionally, the maintaining of a certain level of pressure/expansion ensures that contact with be maintained between the electrode structure and the tissue when during the treatment, the tissue begins to contract due to the energy applied

Regarding claim 3, Stern discloses for the control device to be capable of enabling adjustment of current density of the coagulation current between the electrode and tissue (see col. 10; 14-25).

11. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al (US Pat. Pub. 2003/0130572 A1) as applied to claim 1 above, and further in view of Kordis (US Pat. No. 5,823,189).

Regarding claim 18, Phan discloses the device as shown in the rejection of above claim 1. Phan further discloses the inclusion of a second three-dimensional treatment electrode (basket 50 with electrodes 56) that is capable of conducting an HF coagulation current into said tissue (through electrodes 56). Phan fails to specifically recite the expanding of the second three-dimension treatment electrode to various states. In the document which Phan incorporates by reference with specific regard to the basket structure, Kordis discloses for the basket catheter to consist of a three-dimensional electrode which is expanded to various states by one of continuous or stepwise expansion (see col. 5; 47- col. 6; 28). Therefore, it would have been obvious to one

of ordinary skill in the art at the time the invention was made that the device of Phan, specifically using the basket catheter disclosed in Kordis, would function as claimed to both be expanded to various states and conduct HF current to tissue.

Regarding claim 19, Kordis discloses for the second treatment electrode to be expandable/collapsible by the placement of pressure by a sheath on the splines of the basket defining an interior space (sheath 40, see col. 6; 20-28). While Phan fails to specifically recite that the interior spaces of said first and second treatment electrodes can be placed under pressure independently and expanded to different degrees, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the two structures of Phan, utilizing two different deployment methods, fluid pressure and mechanical force, would function independently of one another and be individually controllable by the user to effectuate a desired level of contact between the target tissue and the first or second treatment electrode.

Regarding claim 20, Phan discloses for the first and second treatment electrodes to be arranged co-axially along a central axis of said apparatus (see figures 4 and 6a).

Response to Arguments

12. Applicant's arguments filed April 30th, 2009 have been fully considered but they are not persuasive.

Regarding Applicant's argument that Swanson fails to disclose such limitations as found in paragraph 1 on page 6 of the Remarks, the Examiner respectfully disagrees. The Examiner has carefully considered the amendment to the claim which has replaced "a three-dimension body" with "a first three dimensional electrode" to determine its effect on the scope of the subject matter therein. It is however, still the Examiner's position that Swanson does teach a three-

dimensional treatment electrode. Given the broadest reasonable interpretation of the claim language, the electrode body 20 in conjunction with the electrode 30 contained within the body effectuating treatment to a target portion of tissue through the conduction of electrosurgical energy via a conductive fluid constitutes a three-dimensional treatment electrode. While Applicant is contending in paragraph 3 on page 6 of the Remarks that only the pores 44 in the body 22 enable the current flow between the electrode 30 and the target tissue, nowhere does the Examiner find in the claim that the exterior of the treatment electrode or the surface element is what imparts the HF coagulation current or is electrically conductive.

Additionally, while Applicant is contending in paragraph 2 on page 6 of the Remarks that Swanson fails to teach the treatment electrode to be capable of being expanded to various states of expansion by one of continuous and stepwise expansion of the electrode, the Examiner respectfully disagrees. It is noted by the Examiner that the body 22 of the apparatus of Swanson is disclosed as expanding/inflating from a collapsed state to an expanded state. At any point during such expanding/inflating the electrode can be considered at a state of expansion such as one-half expanded. Nowhere in the claim does it require that the electrode is inflated/expanded to a state and held at that state. Additionally, it is seen by the Examiner that during the expansion from the collapsed state to the expanded state that such is done in a continuous manner until the expanded geometry is reached (see col. 5; 12-47).

Lastly, with regard to Applicant's argument in paragraph 4 on page 6 that Swanson fails to disclose "the treatment electrode to comprise of one of ... thereby said treatment electrode.", the Examiner respectfully disagrees. As noted above, it is the Examiner's contention that the apparatus of Swanson does consist of a three-dimensional treatment electrode. Additionally, the

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provision in column 5, lines 31-35 of Swanson which states that the electrode initially assumes a collapsed, low profile and then is inflated by the application of internal pressure to an expanded state, in the Examiner's opinion, meets the claim language added from previously pending claim 7 to end of claim 1. It is therefore the Examiner's position for the above proffered reasoning, that Swanson is still a valid anticipatory reference.

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Regarding Applicant's argument in paragraphs 3-6 on page 7 that Koblis fails to anticipate claim 1, the Examiner respectfully disagrees. As noted in the above argument of with reference to Swanson, Koblis is being interpreted in a similar manner to define a threedimensional treatment electrode. Again, nowhere does the Examiner find in the claim that the exterior of the treatment electrode or the surface element is what solely imparts the HF coagulation current or is electrically conductive. With specific regard to the argument that Koblish does not disclose "a hydraulically separate interior space to which an internal pressure can be applied to expand the surface element and thereby the treatment electrode", the Examiner must again disagree. It is the Examiner's position that the inflatable therapeutic element 14 with non-porous region 30, porous region 26 and with electrode 32 functions as such. The porous and non-porous regions are considered a surface element which defines a hydraulically separate space and upon the application of an internal pressure within the two portions, the treatment electrode, considered by the Examiner as the combined functionality between the porous and non-porous regions and the electrode of Phan, is thereby expanded. In view of this reasoning, it is the Examiner's position that Phan is still a valid anticipatory reference.

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Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

- 14. It is noted by the Examiner that the new grounds of rejection under Phan were necessitated by the addition of new claim 18-20. Additionally, the new grounds of rejection under Stern and were necessitated by the redefining of the term "body" in claim 1 to the term "treatment electrode" which changed the scope of the claim
- 15. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD J. HUPCZEY, JR. whose telephone number is (571)270-5534. The examiner can normally be reached on Mon. - Fri. from 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD J HUPCZEY, JR./ Examiner, Art Unit 3739 /Michael Peffley/ Primary Examiner, Art Unit 3739

RJH